# VERMONT2007

# Catamount Health: Immunization Study

Report to the Legislature on Act 191 § 24, 2006 (ADJ) Session

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# **Executive Summary**

As designated by the Secretary of Administration in accordance with Act 191, the Department of Health has undertaken this study to determine how the vision set forth in Act 191 to provide "minimum preventive services starting with immunizations for all Vermonters" can be achieved. The study identified significant risks to the current immunization program for children and serious gaps in immunization services for adults underscoring the importance of this initiative.

The process of planning and implementing a comprehensive program to address the immunization needs of all Vermonters is complex. Models from other states can inform our process, but none appear to fully address Vermont needs. This report proposes modest changes that can be implemented in the next fiscal year and calls for an extended planning process for a comprehensive immunization program. The report makes several recommendations, including:

- Develop a time-framed implementation plan for the comprehensive immunization program.
- Establish a universal vaccine purchase system for adults and children.
- Immunization services must continue to be provided primarily within the individual's "medical home" as a component of on-going primary care with the public health system providing back up "safety net" services.
- Expand the Vermont Immunization Registry law to allow data entry and reporting for adults and data exchange with insurers.
- Undertake a comprehensive array of strategies to increase the rates of immunization.
- Establish authority to issue rules to require appropriate immunization of children in child care facilities; and, ensure regular updates to rules regarding immunizations in child care, schools and colleges.
- Expand the membership of the Immunization Advisory Committee to assure representation by health care providers, insurers, and consumers.

Full report is available at <a href="http://healthvermont.gov">http://healthvermont.gov</a> under legislative reports.

# Introduction

The statement of legislative purpose of Act 191, An Act Relating to Health Care Affordability for Vermonters establishes "... Catamount Health, a comprehensive and affordable benefit plan ... providing minimum preventive services starting with immunizations for all Vermonters;" and, to the extent allowed by the appropriation "...without cost to the individual." The bill calls on the secretary of administration or designee to study methods to ensure that all Vermonters have access to immunizations. This report, prepared by the Department of Health, in consultation with the Immunization Advisory Committee, Vermont insurers and others, fulfills the first step in achieving this visionary goal of the Vermont State General Assembly.

Many states have established a policy to ensure universal access to immunization for children; Vermont is the first to establish such a policy for its entire population. It is an essential investment in our future. In designing a program to achieve these public policy goals, it is critical that components are clearly spelled out, stakeholders are fully engaged, links with other Catamount initiatives, including the Blueprint, are made, and evaluation strategies are in place. This report lays out the broad areas that must be addressed to begin program design, and proposes the immediate steps for State Fiscal Year 2008 and ongoing development and implementation of a comprehensive state immunization program.

<sup>&</sup>lt;sup>1</sup> Act 192, Section 2 Legislative purpose and intent <sup>2</sup> 18 VSA §1130 (b)

"If unmet immunization needs are not identified and addressed, state and national coverage rates, [...] can be expected to decline and preventable disease outbreaks may occur as a result."

Institute of Medicine, 2000<sup>3</sup>

# **Immunization**

#### A Successful Public Health Strategy

Immunizations that protect children and adults from disease are one of the genuine triumphs of basic medical science and the health care delivery system as evidenced by dramatic declines in mortality and morbidity for vaccine-preventable diseases throughout the 20<sup>th</sup> century.

Vaccines are now available for preventing a number of diseases that were once common in children and/or adults (see box). Uniquely, vaccines deliver protection in two ways. A vaccine protects the individual who receives it; and, if enough people in the community are protected, it also protects others who may not be immunized, through "herd immunity".

#### Diseases with Available Vaccines

Chickenpox

Diphtheria

Haemophilus influenzae type b infections

Hepatitis A

Hepatitis B

Human papillomavirus infections

Influenza

Measles

Meningococcal infections

Mumps

Pertussis

Pneumococcal infections

Polio

Rabies

Respiratory syncytial virus infection

Rotavirus

Rubella

Shingles

Smallpox

Tetanus

<sup>&</sup>lt;sup>3</sup> IOM Calling the Shots

The social benefits of vaccines are many: they enhance the length and quality of life, they improve the productivity and social contributions of individuals who would otherwise be burdened by disease, and they reduce medical costs. The economic benefits are illustrated in the table:

#### Benefit of immunization<sup>4</sup>

Vaccine	Investment	Benefit
Diphtheria/Pertussis	\$1.00	\$27.00
Measles	\$1.00	\$13.50

Three factors have contributed to the success of immunization:

- The discovery and commercial production of vaccines.
- The integration of immunization services into the private and public systems of personal health care services.
- The development of a public health infrastructure that can monitor disease patterns, improve immunization coverage rates, and require immunization for high risk settings and individuals (e.g.: students, health care workers).

The combination of these three factors have enabled high levels of immunization coverage for a growing number of vaccines for both children and adults within the United States, across economic and social lines and spanning all racial and ethnic populations.<sup>5</sup> To sustain this success is difficult, requiring constant vigilance to detect signs of erosion and decline in coverage rates among vulnerable populations and taking quick action to remediate problems." 4

<sup>&</sup>lt;sup>4</sup> IOM Calling the Shots p 18-19. <sup>5</sup> CDC, 1998a

#### **Immunization Programs**

The Institute of Medicine has identified five fundamental roles of immunization programs in support of the goal of prevention and control of infectious disease. With reference to state immunization programs, these five roles are as follows:

Assure vaccine purchase. This requires maximum and efficient use of federal and state
resources and coordination with the private sector to ensure an adequate supply of
vaccines to meet the needs of the population.

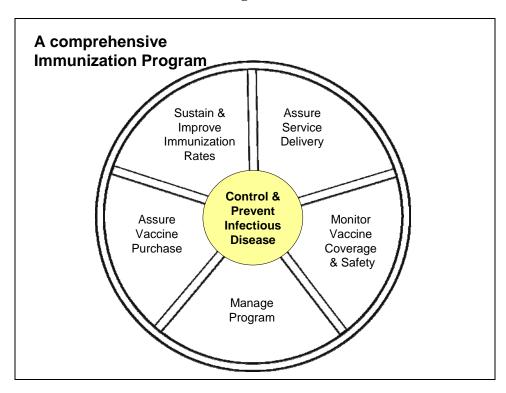


Figure 1

• Assure quality service delivery. This includes services and payments directed to the health care setting to support vaccine administration and ensure vaccines are delivered, handled and stored to maintain efficacy. It also includes supplementation of health care services by public health providers when necessary to ensure full immunization of the population.

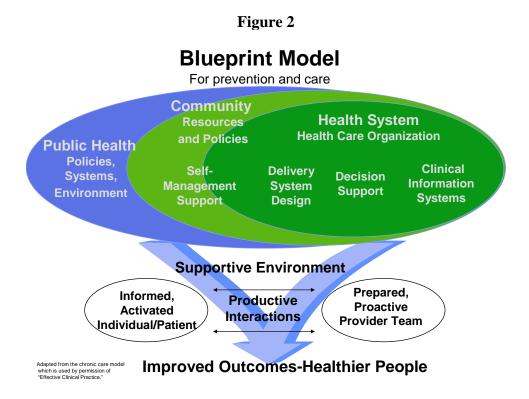
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<sup>&</sup>lt;sup>6</sup> Institute of Medicine. Calling the Shots: Immunization finance policies and practice. National Academy Press. Washington, DC. 2000.

- Monitor vaccine coverage and safety. A comprehensive immunization registry and
  other data sources must be used to monitor coverage, identify gaps in coverage among
  individuals and populations, monitor safety, and report to stakeholders and the public.
- Sustain and improve rates of immunizations. This requires that the program uses its
  registry and other data to sustain coverage and address gaps by employing evidencebased practices for improving immunization rates. Activities must target individuals,
  health care providers, communities and the health system.
- *Program management*. An effective infrastructure must be in place to integrate the other four functions in order to meet program goals, manage implementation, ensure high quality services, and identify and implement effective policies and procedures.

# Blueprint for Health

The Blueprint Model (Figure 2)<sup>7</sup> identifies the core elements for delivery of health services (including immunization) to achieve the goals of improved health outcomes and healthier people.



The same public-private partnership and approach to systems change is needed to ensure that people are fully immunized. **Individuals** must understand the need for and seek out immunization; **Providers** need to be prepared to deliver services according to recommendations; and, the **Community**, **Public Health and Health Systems** must provide the needed infrastructure and supportive environment to reduce barriers and ensure access to immunization.

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<sup>&</sup>lt;sup>7</sup> Blueprint for Health Strategic Plan. Report to the Legislature on Act 191. January 2007. Vermont Department of Health.

# Assuring Vaccine Purchase

#### **Policy for Vaccine Purchase**

States vary in their policies that guide the distribution and use of childhood vaccines. Which policy a given state adopts is generally a reflection of the infrastructure in place to distribute vaccines as well as the availability of funds to finance the purchase of them. See Appendix A for a description of these policies.<sup>8</sup>

The Vermont Department of Health policy has long been to ensure universal access to immunization for all children. In support of this policy, the Vermont Department of Health has directed its federal funding to purchase all recommended vaccines for all children 0-18 years of age. These vaccines are in-turn distributed to some 175 Vermont health care provider sites located at traditional medical clinics as well as Federally Qualified Health Centers, Rural Health Centers and Community Health Centers. Additional amounts are distributed to the 12 Health Department District Offices.

There are a number of benefits to the Vermont policy of universal access for children:

- Enables all children to receive all recommended vaccines at no cost to their parents, providers, or insurance companies.
- Eliminates one of the major barriers to immunization that of having to pay for the vaccine.
- Eliminates the need for multiple vaccine inventory and record-keeping systems within provider offices.

Until the passage of Act 191, Vermont has had no policy to ensure access to vaccines for adults. Currently adult immunization needs are met by insurers, health care providers and consumers. For people who must pay out-of-pocket for all or part of the cost of immunization, access is severely limited. In previous years, before childhood vaccine

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<sup>&</sup>lt;sup>8</sup> Childhood Vaccine Supply Policy – 2005. Centers for Disease Control and Prevention (CDC) National Immunization Program. Available at

costs escalated to the current level, the department directed some of the federal vaccine purchase to adult vaccines.

The policy of universal access to recommend vaccines for children and a reliance on federal funding has some unintended consequences and raises concerns about continuation of this policy in Vermont.

- Federal grant support for purchase of vaccine has not kept up with the increasing number of recommended vaccines and higher costs of the vaccines.
- Nearly half of the total of vaccine purchases in Vermont are for children who have private insurance coverage.
- The federal funds are insufficient to cover both the recommended childhood vaccines and vaccines for adults in need of help to obtain immunization.
- There are a number of vaccines that the department does not purchase and are then paid for by Medicaid, Medicare, insurance or the consumer.

#### **Vaccines for Children**

Several sources exist to assist states to purchase childhood vaccines: the federal "Section 317 Vaccination Assistance Act", the federal Vaccines for Children (VFC) Program, state appropriations, and private sector sources.

Section 317 Vaccination Assistance Act (317 funding): This act was passed in 1963 and established a mechanism whereby states could receive discretionary funding to support the purchase of vaccines for children and adults. There are no restrictions on eligibility to receive vaccines purchased under this program. Because this is a discretionary annual congressional appropriation there have been significant fluctuations in funding levels; funding has not kept up with increasing costs of new vaccines.

Vaccines for Children Program (VFC): This program was established by congress in 1993 to fund state health departments to purchase vaccines for eligible children. Eligible children include those less than 19 years of age and Medicaid enrolled or uninsured; or Native American, Alaska Native; or underinsured and enrolled at a Federally Qualified

Health Center or Rural Health Clinic. This is a mandatory program with a stable and increasing funding stream, though again, increases have not kept up with escalating costs.

*Private sources:* Health care providers purchase child vaccines not provided by the Department of Health Immunization Program, or write prescriptions. This is the same as the system used for purchase of vaccines for adults and is described below.

In 1985 the cost of fully immunizing one child was \$45. As new vaccines have been developed (often at higher costs than existing ones), and as the costs associated with producing existing vaccine increased, the cost of fully immunizing one child has risen to nearly \$900 for males and \$1200 for females in 2006 (Figure 3). <sup>9</sup> These amounts represent the cost of the vaccines only (at federal contract prices) and exclude all other program costs.

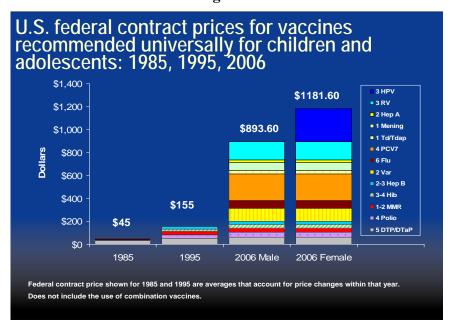


Figure 3

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<sup>&</sup>lt;sup>9</sup> CDC data

Further financial restrictions in the federal programs are expected over the next several years. States will be required to pay *up-front* a percentage of the cost of vaccines which are provided through federal purchasing agreements (i.e. VCF). In calendar year 2006 that percentage was estimated to be 13 percent for Vermont, or roughly \$980,000. There are also restrictions placed on the number of doses of vaccine the Vermont Department of Health Immunization Program can purchase off of the federal contract, and/or the amount of federal funding available for a particular vaccine.

#### Vaccines for adults

There are no state or federal public health programs to ensure purchase of vaccine for adults. Purchase of vaccines for adults is totally within the private sector. Because, most often, relatively small amounts are purchased, the vaccine costs more than when it is purchased through federal contract or other bulk-purchasing agreements. Health care institutions and providers can pass these higher costs onto the patient or to a third party payer when they bill for the immunization. The total spent each year by Medicaid, Medicare, private insurers and consumers is currently unknown.

Purchases are made in two ways, the physician purchases the amount of vaccine he or she estimates will be needed for the patient population, or writes a prescription for the vaccine which the patient has filled at a local pharmacy and brings to the office for vaccine administration. With the increasing number and cost of vaccines, fewer providers are able to purchase all needed vaccines up front, leading to more prescriptions being written.

Vaccine prices can vary widely with the federal contract for the VFC program having some of the lowest costs, somewhat higher costs for other large purchasers such as the Minnesota Multi-State Purchasing Agreement and the highest prices are for individual doses on the retail market (at pharmacies). As an example, vaccine to prevent meningitis costs \$68 per dose from the CDC contract and \$81 per dose from the Multi-State contract. The actual retail price in Vermont is \$105 or more per dose.

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Assuring Vaccine Purchase

Vaccine purchased by physicians is, in most cases, reimbursed by Medicaid, Medicare or private insurance, though the rate for reimbursement may not always cover the full cost of the vaccine. Similarly, vaccine purchased at the pharmacy may be billed directly to Medicaid or insurance, or reimbursed in part or in full. When reimbursement is less than

cost, restrictions on balance billing may preclude the physician or pharmacy having the

full cost of vaccine covered.

For patients without insurance, without coverage for immunization or with large

deductibles, the out-of-pocket costs of paying for vaccine, whether purchased by the

physician or at a pharmacy, can be substantial and lead to the decision not to be

immunized.

Vermont state funds are used to purchase a limited number of vaccines for adults each

year. In CY 2006, the Department of Health Immunization Program purchased \$52,476

in vaccines for state employees. Of that, flu vaccine for state employees cost \$38,215 and

will be reimbursed by Cigna. The remaining \$14,261 paid for rabies vaccine for Fish and

Wildlife staff; and Hepatitis B vaccine for State Police, Correctional Officers and others

whose employment for the state requires it.

Flu vaccine for adults in Vermont is purchased primarily by Visiting Nurse Associations,

Home Health Agencies and private health care providers. Maxim, a national company,

purchases vaccine and operates flu clinics in grocery stores, drug stores and some long

term care facilities in Vermont each year.

Approaches in other New England States

Despite these present and future challenges there are options that can be considered to

help finance the purchase of immunizations for children and adults. Examples developed

in other New England states include the following:

Maine: Individual HMO's contribute funds to a consortium in the amount necessary to

cover the costs of all recommended vaccines for all of their covered children. The state

contributes funds in the amount necessary to cover the cost for those children covered by insurers that do not participate in the consortium. This program was established through an informal agreement between the HMO's and the state.

Rhode Island and Connecticut: Insurers contribute a percentage of their non-Medicaid premiums into a special account whose funds can only be used for the purchase of vaccines for children. Both these programs were established through state statute and insurers are required to participate.

<u>Massachusetts</u>: The state legislature appropriates funds to supplement the purchase of vaccines for children and high risk adults; no funds are collected from the insurers. The level of state funding fluctuates each year.

<u>New Hampshire</u>: Insurers contribute all costs for vaccines for children not covered by the federal Vaccines for Children Program. This system is operated by an independent non-profit agency. This agency annually sets the amount of funds each insurer is required to contribute and coordinates the collection and use of these funds.

#### **Findings:**

- No other state was identified as having a policy or program to ensure immunization for all of its residents.
- At this time, the Department of Health Immunization Program relies solely on federal funding to finance the purchase of all childhood vaccines; additional resources are needed to maintain child immunization rates at the current level and to expand the program to include new vaccines for children as recommended by the Advisory Committee on Immunization Practices (ACIP).
- The Department of Health is able to purchase vaccines at favorable rates through a contract with the Centers for Disease Control and Prevention, and the Minnesota Multistate contract. To date, these contracts are unavailable to the private sector.
- Health insurers pay for only a limited number of vaccines for covered children.

- Cost sharing for childhood immunizations would allow continued universal access, provide the additional resources needed to maintain and improve child immunization rates, and allow the Department of Health Immunization Program to free up 317 funds to purchase some vaccines for adults.
- Medicare and Medicaid are the primary source of public support for immunization services for adults.
- Health care providers and consumers purchase nearly all adult vaccines, generally at prices that are considerably higher than what the state may be able to negotiate.
   Reimbursement levels may differ by insurance plan and lead to significant out-of-pocket expense by consumers and/or providers.
- Use of the State's ability to purchase vaccines for adults at favorable rates for all
   Vermonters would significantly reduce the costs to providers, consumers and insurers,
   and lead to improved rates of immunization and much lower risk of disease.

# Assuring Service Delivery

Assuring that vaccines are properly administered to adults and children consistent with recommendations for age, gender and risk status is largely the responsibility of the health care system and health care providers. Maintaining records of immunization is a shared responsibility between the provider and the individual or his/her parent or guardian.

#### **Provider Practices**

In Vermont, the primary care system, public and private, administers nearly all immunizations for children and adults. Approximately 98 percent of vaccines administered to children are provided at their medical home; and the vast majority of adults receive all of their needed immunizations from their primary care provider. The major exception is the wide-spread use of "flu clinics" held each fall and winter. As the cost of vaccine increases and reimbursement is uncertain, Vermont's reliance on the primary care system to ensure that immunization services are provided is under increasing pressure.

#### **Public Health System**

The 12 Department of Health District Health Offices are an essential "safety net" resource for immunization when primary care services are not available or accessible. Fewer than 2 percent of children and a small number of adults receive their immunizations from public health nurses each year. The most common need is for the public health nurses to immunize uninsured adolescents who need a tetanus booster or a Hepatitis B immunization to meet school requirements. The *varicella* vaccine is extremely fragile needing to be maintained at temperatures below freezing and few providers have an office freezer that meets this requirement; when this is the case, public health nurses are available to administer the immunization. Public health nurses also administer rabies and Hepatitis B immunization to state employee's who must be protected under OSHA rules; and annual flu vaccine for all state employees.

The Vermont home health care agencies in collaboration with the Department Immunization Program offer flu immunization clinics statewide each year. The home health agencies purchase vaccines and manage clinic operations with the Department of Health providing supportive services including announcement of clinic dates and locations on the Health Department website and public service announcements encouraging people to get their flu shots.

#### **Controlling Disease Outbreaks**

The Infectious Disease Epidemiology Program of the Department of Health is responsible for identifying disease outbreaks and notifying the Immunization Program and district health offices. When the Immunization Program is notified of an outbreak of a vaccine-preventable disease, such as meningitis or Hepatitis A, both programs rapidly mobilize to determine the need for vaccine or immune globulin, if appropriate. In collaboration with the district office, and with thorough contact tracing, appropriate supplies are moved to the location where they are needed, and the vaccines or gamma globulin are administered either through the person's own primary care provider or by public health nurses. The district office staff also takes responsibility for educating exposed community members regarding risks for contracting the disease and the personal and community benefits of immunization.

The departments Immunization Program and district health offices respond to several outbreaks of disease each year. They must also be prepared to respond to a wide-spread outbreak or pandemic that would put all Vermonters at risk. When large numbers of people must be immunized in a short period of time, district office public health nurses organize clinics, arrange for additional volunteer nurses, educate community members, conduct case investigations and immunize Vermonters.

### Health Provider Office Systems to Ensure Service Delivery

As with chronic disease management, preventive care is planned care and much of the work of ensuring that people receive needed immunizations falls to the individual provider and practice team. As related to immunization, it requires they keep apprised of recommendations for each vaccine by age and risk factor, have available the decision support tools to enable use and the office systems to deliver the care. Providers must also guide and coach patients regarding immunization and link them to public health back-up services when indicated. A clinical information system is one essential tool that supports all of these requirements.

Information technology is a key component of the Vermont Blueprint for Health Model to ensure that health care providers have available patient data from the medical record (electronic or paper), coordinated with practice guidelines such as the ACIP recommendations for immunization, and adapted to office work flow. The system must produce individual and practice population reports with these data also available for monitoring progress and evaluation.

#### **Immunization Registry**

Vermont has a statewide Immunization Registry - a web-based repository of immunization records of Vermont children. This registry offers a number of strengths over traditional paper-based systems for recording immunization and gives the health care provider a powerful tool that incorporates decision support guidelines and supports office system strategies that help ensure that children are adequately and appropriately immunized.

Immunization records are easily accessible by health care providers, even if a child is a new patient. This reduces the likelihood of over-immunization and/or minimizes the need for return visits as the provider waits for the child's medical history to arrive from a previous provider. As of January 2007, the registry will include a reminder/recall system

**Assuring Service Delivery** 

to inform clients they are due or overdue for specific immunizations. It provides guidance around the timing of specific immunizations, based on the child's age, the child's specific immunization history, and the ACIP guidelines.

Vermont's immunization registry will need to be modified to include adult immunization recommendations and records and to allow data to be entered by insurers. The current law also needs to be modified to allow sharing patient specific data in the registry with insurers.

#### Blueprint for Health Chronic Care Information System (CCIS)

The Chronic Care Information System has the capacity to include immunization guidelines and data, produce reports, issue reminders; and has the potential to transfer information to and from the immunization registry and to insurers. This data exchange is the responsibility of Vermont Information Technology Leaders (VITL). Seamless interface for providers between electronic medical records, the immunization registry and insurance records is essential to ensuring use of all these systems in the practice.

#### Findings:

- Vermont's universal status for providing immunizations to children is in jeopardy due
  to the reliance on federal funding to cover costs. Cost sharing will be essential to
  continue to maintain this policy. (See Vaccine purchase above.)
- The partnership of primary care to administer vaccines and the state to purchase and distribute them has been successful in ensuring access to immunization and a generally high rate of immunization for children; a similar partnership for adults has the potential to be equally successful.
- Public health nurses provide essential safety-net services for immunization. This service must be maintained, and may need to be expanded to ensure access to immunization for all adults and children.

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**Assuring Service Delivery** 

- Office system tools to assist providers in assessing and improving the delivery of immunizations are essential to ensuring that people get the immunizations they need at the appropriate time.
- The immunization registry statute needs to be updated to include adult immunization records and allow data exchange with insurers. The Vermont Blueprint for Health CCIS work plan and VITL information technology plan will both need to be modified to include interface with the immunization registry.

# Monitoring Vaccine Coverage and Safety

#### **Vaccine Coverage Data Sources**

A number of data bases are used to monitor vaccine coverage:

- The National Immunization Survey (NIS) is a random-digit dial telephone survey followed by a mailed survey to health care providers. The purpose of the NIS is to produce estimates of vaccination coverage for all recommended childhood immunizations for children between the ages of 19 and 35 months.
- Behavioral Risk Factor Surveillance System (BRFSS), a telephone survey of adults ages 18 and over, is used to assess health risk behaviors, use of clinical services, and access to other health care services. It specifically asks about status of immunization for influenza and for pneumococcal infections.
- Health Plan Employer Data Set (HEDIS<sup>®</sup>) contains information from managed health plans on a number of measurable outcomes including immunization coverage levels for enrollees.
- Assessment, Feedback, Incentives and Exchange (AFIX) Program is a national quality improvement program that seeks to raise immunization coverage rates within provider practices. It includes activities to assess immunization coverage within provider practices, provide feedback to provider practices to improve delivery of immunizations, provide incentives to recognize and reward improved performance, and exchange information among providers.
- Vermont Immunization Registry: Established by statute, the registry is designed to collect immunization records on Vermont children.<sup>10</sup> The registry can be a useful tool for monitoring immunization coverage rates within specific health care practice sites and among specific populations or groups.

# **Vaccine Safety**

The *Epidemiology and Prevention of Vaccine-Preventable Diseases* states the following in regards to vaccine safety: "Vaccine safety is a prime concern for manufacturers, immunization providers, and recipients of vaccines. Vaccination is among the most

<sup>&</sup>lt;sup>10</sup> 18 V.S.A. §1129.

significant public health measures however like any pharmaceutical product, no vaccine is completely safe or completely effective. Maintaining public confidence in immunizations is critical for preventing a decline in vaccination rates that can result in outbreaks of disease."<sup>11</sup>

Unlike medical interventions given to ill people to treat disease, vaccines are given to healthy people to prevent disease. Though much can be learned about the safety of vaccines during the pre-licensure clinical trials, less common adverse events may occur post-release that were not be detected in the trials. Therefore, systems must be in place to monitor for these events after the vaccines become widely used. An example of such a system is the Adverse Events Reporting System (VAERS), a surveillance system developed by the Centers for Disease Control and Prevention (CDC) for the reporting and follow-up of adverse events. The success of this system is illustrated by its detection of an increase in a certain gastrointestinal complication associated with use of a new rotavirus vaccine; after further follow-up the vaccine was removed from the market.

In Vermont, providers and consumers are encouraged to report adverse events using VAERS. In addition, the immunization registry includes specific information about the vaccine, such as its lot number, facilitating the identification of children who received a vaccine that later may be discovered to have limited effectiveness or safety issues.

#### **Findings:**

 Mechanisms are currently in place to monitor vaccine coverage and safety in adults and children.

 Expanding the immunization registry to adults would provide an important tool for monitoring adult coverage for all recommended vaccines.

<sup>&</sup>lt;sup>11</sup> Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Atkinson W, Hamborsky J, McIntyre L, Wolfe S, eds. 9<sup>th</sup> ed. Washington DC: Public Health Foundation, 2006.

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Monitoring Vaccine Coverage and Safety

- The Vermont Blueprint for Health CCIS has the potential to provide essential, seamless interface for data entry into the immunization registry, particularly for adults.
- Data exchange with insurers would enhance monitoring of immunization rates and opportunities to improve systems to include rates of immunization for all populations.

# Sustaining and Improving Rates of Immunizations

#### **Vermont Immunization Rates**

- In 2005, 81.5 percent of Vermont children between 19 and 35 months of age were up-to-date for all recommended vaccines <u>excluding varicella</u> (chickenpox); the national average was 80.8 percent (NIS).
- In 2005, 62.9 percent of Vermont children between 19 and 35 months of age were upto-date for all recommended vaccines <u>including varicella</u> (chickenpox); the national average was 76.1 percent (NIS). Vermont is ranked last among all states and the District of Columbia. The Healthy Vermonter goal is that 90 percent or more of children will be fully immunized by age 2 years.
- Assessment, Feedback, Exchange and Incentives (AFIX) surveys in 2006 found 10 practice sites out of 161 met or exceeded the Healthy Vermonter goal of 90 percent or more of children being fully immunized by age 2 years.
- HEDIS data of insured children has similarly low rates (see table) among Vermont insurers.

Vermont HEDIS Reports by Insurance Plan2005 <sup>12</sup>							
	BCBS	CIGNA	MVP	TVHP	Regional Average	National Average	
Childhood Immunizations	60%	71%	70%	61%	81%	78%	
Adolescent Immunizations	50%	59%	69%	45%	77%	54%	
Flu Shot for Ages 50-64 (CAHPS Q 51)	35%	51%	40%	39%	38%	36%	

 Among 2 year old children enrolled in WIC, 93 percent are up-to-date on immunization, the highest proportion in any WIC program in the United States.

<sup>&</sup>lt;sup>12</sup> Evaluation of the 2006 Rule 10 Managed Care Plan Data Filing. Vermont Department of Banking, Insurance, Securities and Health Care Administration, October 2006. For children the measure is the proportion fully immunized for all recommended vaccines (including *varicella*) at age 2; for adolescents, the proportion fully immunized for all recommended vaccines at age 13; and for adults, a two year rolling average of the proportion of adults ages 50-64 who received flu shots.

At entry to kindergarten immunization rates are high: 96.3 percent for polio; 96.9 percent for Diphtheria/Tetanus (Dtap/DT/DPT); and, 93.6 percent for measles.

- In 2004, 66.3 percent of adults ages 65 and older reported they had a flu shot in the past year, compared to 72 percent in 2002. The national rate is 65.5 percent (BFRSS); the Healthy Vermonter 2010 goal is 90 percent.
- HEDIS data of insured adults ages 50 to 64 indicates relatively low rates of immunization for influenza in this age group with only CIGNA beneficiaries significantly higher than the regional and national averages.
- In 2005, 66.7 percent of adults ages 65 and older reported they had ever had an immunization for pneumococcal infections. This rate has been essentially level for several years; the national rate is 65.5 percent. (BFRSS) The Healthy Vermonter 2010 goal is 90 percent.
- There is no data on the proportion of people in particular high risk groups that have received recommended immunizations. (e.g., Hepatitis B for drug users, incarcerated people and other high risk groups)
- Human Papillomavirus (HPV) and shingles vaccine are new and few Vermonters have been immunized as recommended.

#### **Barriers to Immunization**

Several factors are believed to contribute to the generally low rates of immunization in Vermont. These include:

- Costs: Particularly for adult vaccines and when child vaccines are in short supply, the out-of-pocket cost of vaccine leads to fewer people immunized. Uncertain or inadequate reimbursement means fewer health care providers stocking vaccines, particularly high cost vaccines.
- Outdated school entry requirements: Vermont regulations have not been updated to include *varicella* immunization.
- Inadequate recall and reminder systems in physician offices: Use of out-dated forms that do not list *varicella*; failure to record all immunizations in a single place in the health record; a lack of standing orders for immunization that allow nurses to provide

the immunizations; and the need to develop office based systems lead to widespread variability in practices with resulting low immunization rates.

- Community and individual concerns: Inaccurate information regarding the importance of immunization and the safety of vaccines undermines acceptance and leads to lower rates of immunization among vulnerable parents and caretakers.
- Uncertain supply: In the case of influenza, the problems of vaccine supply over the past 3 years, has confused the public and led to fewer people being immunized.
- HPV immunization: Supply and distribution of HPV vaccine is a particular concern at this time. An estimated 83,000 Vermont females are in the eligible age group to receive the vaccine. The total cost to immunize this number of women could exceed \$27 million in vaccine costs alone. The vaccine protects against four major types of infection that are responsible for about 70 percent of cervical cancer and 90 percent of genital warts in women. Active marketing by the manufacturer is creating a high demand for this vaccine.<sup>13</sup>

#### Strategies for Improving Rates

The "Guide to Community Preventive Services" addresses the effectiveness of population-based interventions to increase immunization coverage.<sup>14</sup> The guide identifies 10 interventions that have strong or sufficient evidence that they will be effective. These are summarized in Appendix A. Other interventions such as education, incentives and school-based programs may also be effective although additional research is needed.

<u>Immunizations Required for Childcare, School and College Attendance:</u> Requiring immunization is an effective strategy in increasing immunization rates. Vermont law authorizes the Health Department, through the rule-making process, to set requirements for children who are enrolling in kindergarten, elementary and secondary school and any post-secondary school<sup>15</sup>. These requirements were last updated several years ago and as

<sup>&</sup>lt;sup>13</sup> Eradication of Cervical Cancer. Report to the Legislature on Act 110. Vermont Department of Health.

<sup>&</sup>lt;sup>14</sup> Guide to Community Preventive Services, http://www.thecommunityguide.org/vaccine/ <sup>15</sup> 18 V.S.A. §1120 – 1129.

Sustaining and improving Rates of immunization

such do not reflect the most current recommendations set forth by the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP). The lack of current regulations for *varicella* immunization for example, is believed to be a major contributor to Vermont's slide in ranking from one of the top states in the nation to last in the proportion of children who are fully immunized. Additionally, there is no statutory authority given to the Health Department or any other state agency to set requirements for children enrolling in child care facilities.

Enhancing access to vaccination services. One of the most significant barriers to immunization is cost. When out-of-pocket expenses are reduced through free or low cost programs and insurance coverage is ensured, rates of immunization are improved. The Vermont policy of universal access to vaccines for children, in combination with other interventions, resulted in high immunization levels in the past. Act 191 which calls for universal access to free immunization is a visionary initiative to extend this benefit to adults.

Another successful strategy is to assist people to access immunization services. One role for Health Department district office staff is to help children enrolled in WIC to enroll in a medical home if they are in need of one and to monitor their immunization status. Public health staff have been instrumental in assuring that 93 percent of 2 year old children enrolled in WIC are up-to-date on their immunizations.

Recall/Reminder Systems: As in the management of chronic disease, provider and client-based recall/reminder systems for immunization are essential tools for ensuring office systems support high quality care. Immunization rates have been demonstrated to rise with implementation of such systems. As of January 2007, the Vermont Immunization Registry has the capacity to generate reports that can initiate a recall/reminder when a particular vaccine is due.

#### Findings:

- Vermont has the lowest rate of fully immunized children in the nation, due primarily to inadequate immunization against *varicella*. This is an unacceptable finding for a state that is generally in the top 10 for health status indicators; more aggressive steps should be taken to assure children are vaccinated against *varicella*.
- Vermont immunization rates for influenza and pneumoccoccal infections among adults are low and there has been no progress in improving them for several years, both remain far below Healthy Vermonter goals.
- Vermont rules for immunization requirements for kindergarten, elementary and secondary schools and post-secondary schools are out-of-date and need to be revised to reflect the most current recommendations set forth by the Advisory Committee on Immunization Practices (ACIP).
- The immunization law must be amended to establish immunization requirements for child care facilities.
- While Vermont has several strategies in place to improve immunization coverage, a comprehensive, strategic planning effort, integrated with the work of Vermont health plans, is needed to ensure a continuously updated, efficient approach to individuals and providers and promote community understanding and acceptance of immunization.

## Managing An Immunization Program

Program management integrates vaccine purchase, service delivery, monitoring and improvement of coverage rates into a comprehensive approach. In Vermont, the Health Department's Immunization Program is responsible for performing these activities. It has a full time, core staff in the central office responsible for program oversight and coordination, vaccine purchasing, quality improvement, monitoring, education of health care providers and the public, registry management and coordination between public health and health systems. In addition, two full time equivalent information systems developers work on registry design and enhancement.

Each Health Department district office has a part time public health nurse and clerk designated to be responsible for local immunization program activities. These staff are responsible for receiving and redistributing vaccines to health care providers in the district, conducting AFIX audits (see quality control), immunizing children with no medical home, and monitoring immunization records of children who participate in the Women's, Infant and Children (WIC) program. There are currently four FTE nurses and one FTE clerk distributed across 12 district offices.

## **Quality Assurance and Quality Improvement**

The goals for quality control in the Department of Health Immunization Program are fourfold:

- Ensure that viability and efficacy of vaccines is maintained at all times. Vaccines must be maintained within the recommended temperature range and administered before the date of expiration.
- Minimize waste caused by improper handling and poor inventory control. Improper handling and allowing vaccines to out-date significantly increase costs to the program.
- Achieve a high degree of accuracy and completeness of all immunization records.
   Ensuring safety requires proper documentation of immunizations have been given and that allows tracking of manufacture and lot number to each individual receiving that

vaccine. This information should follow the individual when seen by different providers.

 Ensure that vaccines are administered on schedule, in keeping with the recommendations of ACIP, and accurately recorded. Poor record keeping frequently leads to unnecessary re-immunization and increased costs to the program overall.

Three strategies are employed by the Vermont Immunization program to meet these quality goals.

AFIX (Assessment, Feedback, Incentives and exchange): This program is used to assess the immunization coverage rates for selected age groups and immunizations. This program, mandated by CDC, assesses practice level reports that are shared with the practice as part of feedback. Barriers to complete up to date immunization within the practice are identified. Strengths and areas of improvement are acknowledged and strategies to improve immunization services are suggested. Practices with high coverage rates or that improve their coverage are given incentives. Information concerning state trends and solutions is exchanged with providers.

Vaccines for Children Guide to Best Practices: This comprehensive program includes on-site visits to practices by district or central office staff who evaluate immunization storage and handling, documentation of vaccine eligibility and vaccine administration, compliance with federal regulations, provide education and distribute a handbook on "best practices". When monitoring of these programs became possible in 2002, a number of errors in vaccine handling, storage, administration and documentation were discovered and corrected in pediatric and family practice sites statewide.

**Vermont Immunization Registry:** Most documentation issues can be addressed by consistent use of the Registry for each immunization at the time the vaccine is administered to a patient.

### **Financing**

The Department of Health Immunization Program has a 2007 budget of approximately \$9 million, funded from the Center for Disease Control. This covers the full range of immunization program functions including, until recently, the purchase of an adequate supply all recommended childhood vaccines. The private sector (individual consumers, health care providers and payers) maintains a separate financing structure for adult vaccines, child vaccines not supplied by the department, and the costs to the primary care provider to administer the vaccines. In some states, legislative appropriations and/or cooperative public-private vaccine purchasing agreements provide additional financial support.

The cost of a comprehensive program cannot be estimated with any certainty at this point in time. We know what the Department of Health Immunization Program pays for now, but need similar information from Medicaid, Medicare and other insurers to determine what their costs are. We need to verify early estimates of the additional funds needed to maintain universal access for children and to meet the goal of 90 percent of children fully immunized. For adults, we need to ascertain the coverage rate that has been achieved with the current investment by consumers and insurers and estimate the additional costs of meeting similar immunization goals for adults. The addition of adult immunization to the departments current program will require increased district and central office health office staff to manage the program, ensure quality, provide training and maintain the expanded registry.

## **Advisory Committee**

Immunization Advisory Committee, whose members include pediatricians, family practitioners, infectious disease experts and other health care providers serve to advise the department on a number of important issues related to childhood immunizations. The Committee has no consumer, insurer or employer members.

#### **Findings**

- Program staff and infrastructure are adequate to support the childhood immunization program at this time; however, impending changes in federal support will strain capacity to purchase vaccines for children within the year.
- There is limited programmatic infrastructure or funding to support adult immunization activities; expansion to include adult services will require significant additions to the current program.
- Public-private cost sharing agreements such as used for child vaccine purchase programs in other states has the potential to provide adequate resources to address program management needs as well as vaccine purchase.
- The introduction of new vaccines present unique problems for program management due to higher costs, demands on the program to develop new systems for unique population groups, and the need to "catch up" significant numbers of people.
- HPV immunization presents particular challenges to ensure an adequate supply of vaccine, ensure equitable access by girls and women regardless of income and insurance status, and cover the significant costs associated with the vaccine.
- The current Immunization Advisory Committee focuses on child immunization issues and membership is limited. Expansion of the program to include adults and to ensure support and participation by insurers will require restructuring and additions to the committee.
- The quality assurance/quality improvement activities undertaken by the Department of Health Immunization Program have been effective in addressing deficiencies related to the storage, handling and administration of childhood immunizations in provider practices and can serve as a model for similar activities related to adult immunization.

# Study Recommendations

To accomplish the goal set forth in Act 191 to provide "minimum preventive services starting with immunizations for all Vermonters", Vermont should implement a comprehensive immunization program, serving both adults and children, and funded at a level to support all functions of an immunization system.

- 1. Develop a comprehensive, staged plan for implementation
  - 1.1. Include all components of the comprehensive immunization program:
    - 1.1.1. All five functions of an immunization program (vaccine purchase, service delivery, monitoring of coverage and safety, improvement in rates of immunization and program management).
    - 1.1.2. An integrated financing model using resources from the private sector as well as public funds.
    - 1.1.3. An effective and adequate system of payment to health care providers including incentives to achieve a high rate of immunization in their practice.
    - 1.1.4. A comprehensive quality assurance/quality improvement program to assure vaccine effectiveness.
    - 1.1.5. An effective oversight process to allow participation by all public and private entities responsible for program success.
  - 1.2. Convene a task force of essential stakeholders to guide and advise on program design, policies and implementation
    - 1.2.1. Use in-depth analysis of immunization status, utilization rates and gaps, to guide program design and ensure that all Vermonters can access immunization services.
    - 1.2.2. Ensure that the needs of people served by state programs are addressed within the system or in coordination with the private sector (e.g., children in custody, Community Rehabilitation and Treatment service recipients, incarcerated people).

- 1.2.3. Develop recommendations for integration with self-insured health plans, state and federal health plans (Medicaid, Medicare, Veterans, etc.).
- 1.2.4. Present a complete, multi-year budget for the program and a phased rollout that ensures full implementation.
- 1.3. Implement components of the Vermont Immunization program with first phase beginning in the current year and continuing in state FY 2008.
  - 1.3.1. Provide basic immunization coverage for people enrolled in the Catamount Health Plan including vaccine purchase and payment for administration of vaccines.
- Establish a universal vaccine procurement and management system for adults and children, and including the costs of purchase, storage, distribution and quality assurance.
  - 2.1. Establish mechanism for insurer contribution for vaccines for covered children and adults
    - 2.1.1. Use the Minnesota Multi-state contract or similar bulk purchasing agreement to obtain a pricing system favorable to participation by insurers in Vermont.
  - 2.2. Continue to use Vaccines for Children (VFC) funding to purchase immunizations for VFC-eligible children, using the federal contract to the extent allowed.
  - 2.3. Direct Section 317 funding to purchase vaccines for special populations not covered by the private, federal or state appropriations (e.g.: Medicare, incarcerated people).
  - 2.4. Establish an annual state appropriation to support Catamount beneficiaries, and other costs per the proposed budget to meet the goal of access to immunization for all Vermonters.

Statutes and resources needed: Participation by insurance companies will be needed to accomplish this recommendation

3. Continue Vermont's commitment to ensuring that immunization services be provided within the individuals "medical home" as a component of on-going primary care and preventive health efforts.

Statutes and resources needed: none at this time

- 4. Continue to assure the public health system to serve as the "safety net" to provide immunizations when they cannot be provided in the primary care setting.
- 5. Expand the Vermont Immunization Registry to allow data entry and reporting for adults and data exchange with insurers.
  - 5.1. As a component of the state immunization plan, the relationship of the Immunization Registry to the Blueprint Chronic Care Information System (CCIS) and the role of VITL should be described; and strategies and time frames for linking these two critical data sets identified.

Statutes and resources needed: none in FY 08: authorization to establish additional public health nursing positions to do more immunizations and undertake quality control measure with providers may be needed depending on the comprehensive plan

- 5.2. In collaboration with the Blueprint and with VITL, develop data exchange services to provide insurers with data on immunizations provided to their beneficiaries, allow them to monitor immunization status within their plan, and to coordinate improvement strategies with the Vermont Immunization program.
  Statutes and resources needed: Amend 18 V.S.A. §1129 to include adults and data
- exchange with Vermont insurers.
- 6. Develop enhanced education and outreach measures effective in increasing rates of immunization including community programs to increase understanding of and demand for immunization, enhancing access to immunization and assisting providers to make needed changes in office systems.

Statutes and resources needed: Outreach and education resources as a component of the overall comprehensive plan

7. Update existing immunization legislation to require appropriate immunization of children in child care facilities.

Statute Changes: Amend 18 V.S.A. § 1120 to § 1130 to add child care.

- 8. Ensure regular updates to rules regarding immunizations in child care, schools and colleges and recommend changes to statute when needed.
  - 8.1. School entry requirements will be reviewed and up-dated annually in time for the start of the academic year.
  - 8.2. College entry requirements will be reviewed and updated as needed for the academic year.

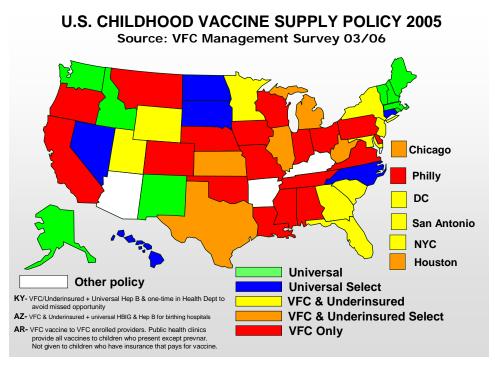
Statutes and resources needed: none at this time

- 9. Redesign the Immunization Advisory Committee to include a core committee focused on all immunization issues with three standing committee's focused on child immunization, adult immunization and the vaccine purchasing agreement. Task forces would be formed for particular purposes when needed.
  - 9.1. Membership on the Advisory Committee would include physicians and other health care providers, insurers, employers and consumers.
  - 9.2. The Immunization Advisory Committee should convene Task Forces to address each of these issues, recommend strategies, and ensure implementation of measures to address these problems.

Statutes and resources needed: none at this time

## **Appendix A**

#### State Policies for Distribution and Use of Childhood Vaccines<sup>16</sup>



- <u>Universal</u>: State immunization program supplies all childhood vaccines to all providers;
- <u>Universal-select</u>: State immunization program supplies all vaccines to all providers with the exception of one or more vaccines;
- <u>Vaccines for Children and underinsured</u>: State immunization program supplies all vaccines for VFC-eligible and underinsured children to all VFC-enrolled providers;
- <u>Vaccines for Children and underinsured-select</u>: State immunization program supplies most vaccines for VFC-eligible and underinsured children to all VFC-enrolled providers;
- <u>Vaccines for Children only</u>: State immunization program supplies VFC vaccine to all VFC-enrolled providers;
- Other: A combination of policies not described above.

 $<sup>^{16}</sup>$  Childhood Vaccine Supply Policy – 2005. Centers for Disease Control and Prevention (CDC) National Immunization Program.

# **Appendix B**

# Summary of Successful Strategies to Increase Immunization Rates<sup>17</sup>

Intervention	Description	Benefit				
Increasing community demand for Vaccination						
Client Reminder/Recall	Systems to inform clients they are	8-16 percentage				
systems	due or overdue for specific	point				
	vaccinations using phone or mailed	improvement in				
	items.	coverage				
Education in combination	Target populations receive education	15 percentage				
with other interventions	about vaccinations via various media	point				
	AND one or more additional	improvement				
	intervention (e.g.: expanded hours,					
	reminders, reduced out-of-pocket					
	costs).					
Requirements for childcare,	Laws requiring proof of immunity	15 percentage				
school and college	before attendance	point				
attendance		improvement				
<b>Enhancing Access to Vaccin</b>	Enhancing Access to Vaccine services					
Reducing out-of pocket	Providing free vaccination, improving	15 percentage				
costs	insurance coverage or reducing co-	point				
	pays	improvement				
Expanded access in	Vaccinations offered in more	12 percentage				
combination with other	convenient or new setting, or at	point				
interventions	increased hours; AND one or more	improvement				
	additional intervention (e.g.:					
	education, reduced out-of-pocket					
	costs, standing orders)					
Programs in WIC settings	Identifies at-risk children with	4-34 percentage				
	referral to a health care provider; may	point				
	also include education, on-site	improvement				
	provision of vaccination or incentives					
Home visits	Face to face services in the home,	10 percentage				
	may include education, assessment,	point				
	referral or giving the vaccine in the	improvement				
	home	_				

<sup>&</sup>lt;sup>17</sup> CDC, community Prevention Services: Immunization

Provider Based Interventions				
Provider Recall/Reminder	Systems to inform providers of	14-17 percentage		
systems	individual clients that are due or	point		
	overdue for specific vaccination by	improvement		
	flagging charts, computerized			
	reminders and other means			
Assessment and Feedback	Monitoring performance of providers	16-17 percentage		
	in delivering one or more vaccines to	point		
	a client population and giving this	improvement		
	information to the provider			
Standing orders for adult	Programs to allow non-physician	30-81 percentage		
vaccination	medical personnel to prescribe or	point		
	administer vaccines without direct	improvement		
	physician involvement at the time of			
	visit			